REMARKS

The specification is amended to provide sequence identifiers and headings for various sections of the application. The amendments to the specification do not add new matter.

In addition, Applicants have amended Claim 1, and Applicants have added new Claims 33 and 34. Support for the amendments and new claims can be found, for example, at pages 7-8 of the specification. The amendments and new claims add no new matter and are fully supported by the specification, claims, and drawings as originally filed.

Upon entry of the foregoing amendments, Claims 1-18 and 21-34 are pending in the application and are presented for examination.

Sequence Listing

The Office Action objects to the specification for reciting sequences with no sequence identifiers. Applicants hereby submit a Substitute Sequence Listing including 1 additional sequence which was disclosed in the specification, but not presented in the initial Sequence Listing. I hereby state that the amendment, made in accordance with 37 C.F.R. § 1.825(a), included in the Substitute Sequence Listing are supported in the application as filed, for example, at page 22 of the specification.

Upon entry of the amendments to the specification as described above and upon the submission of a Substitute Sequence Listing described above, Applicants submit that the present application now complies with 37 C.F.R. § 1.821(d), as sequence identifiers are now used in all instances where the description or claims of the patent application discuss sequences. In particular, Applicants have amended the specification at page 19 (last full paragraph), page 20 (first full paragraph), at page 20 (second full paragraph), and at page 22 (paragraph spanning pages 21-22) to include the appropriate sequence identifiers. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

Embedded Hyperlink

The Office Action objects to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code. Upon entry of the amendments to the specification as described above, Applicants submit that the present application now complies with MPEP §608.01. In particular, Applicants have amended the specification at page 8 (second

full paragraph) to delete the hyperlink and/or other form of browser-executable code. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

Arrangement of the Specification

The Office Action objects to the specification for lacking the following sections: CROSS-REFERENCE TO RELATED APPLICATIONS; STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT; THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT; INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC; BACKGROUND OF THE INVENTION – Field of the Invention, Description of Related Art; BRIEF SUMMARY OF THE INVENTION; and BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS.

Upon entry of the amendments to the specification as described above, Applicants submit that the present application complies with 37 CFR 1.77(b). In particular, Applicants have amended the specification to include appropriate section headings.

Regarding the CROSS-REFERENCE TO RELATED APPLICATIONS section, Applicants note that in a Preliminary Amendment dated April 5, 2006, Applicants amended the specification to include the following paragraph at page 1, prior to the first paragraph:

> "This application is the National Stage application under 35 U.S.C. §371 of PCT Application No. PCT/EP/2004/011214, filed October 7, 2004, and published on April 21, 2005 as WO 2005/035766, which claims priority to German Application No. 103 46 611.8, filed October 7, 2003."

Regarding the NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT section, Applicants note, as stated in §1.71(g), the "specification **may** disclose or be amended to disclose the names of the parties to a joint research agreement (35 U.S.C. 103(c)(2)(C))." [emphasis added]. Accordingly, this section appears to not be mandatory, and can be included at any time during the pendency of the application. As such, this section is not included at this time.

Regarding the BRIEF DESCRIPTION OF THE DRAWINGS section, Applicants note that although this section does not fall within the precise ordering of the specification described in the guidelines under 37 CFR §1.77, 37 CFR §1.77 does not require this precise arrangement of the specification. 37 CFR §1.77 merely states that the "specification **should** include the

following sections in order." [emphasis added]. In addition, MPEP § 601 states that the guidelines regarding the arrangement of the specification "illustrate the **preferred** layout and content of patent applications" and the "guidelines are **suggested** for the applicant's use." [emphasis added]. Accordingly, Applicants submit that the present application complies with 37 CFR §1.77(b). As such, Applicants respectfully request reconsideration and withdrawal of this objection.

Objection of Claim 1

The Office Action objects to Claim 1 for reciting "the gene GSTA1" and "the gene WIR1a" which imply that there is only one GSTA1 gene and one WIR1a gene.

Applicants have amended Claim 1 to recite "a GSTA1 gene" and "a WIR1a gene." As such, Applicants respectfully request reconsideration and withdrawal of this objection.

Discussion of Rejection Under 35 U.S.C. § 112, first paragraph - Enablement

Claims 1, 3-18, and 21-32 are rejected as allegedly not being described in the specification in such a way as to enable the skilled artisan to make and use the invention commensurate in scope with the claims. The Office Action states that the specification is enabling for a recombinant promoter comprising the promoter sequence of SEQ ID No. 1 and the intron sequence of SEQ ID No. 2, a chimeric gene comprising said recombinant promoter operably linked to a coding sequence of interest, a method of transforming a plant with said chimeric gene, and a transgenic plant and progeny thereof comprising said recombinant promoter or chimeric gene. However, the Office Action states that the Applicants have not provided guidance for teaching all promoters from the GSTA1 genes and all introns from WIR1a genes.

In view of the presently pending claims, Applicants respectfully traverse.

An application enables the claims "if one skilled in the art, after reading the[ir] disclosure[s], could practice the invention claimed ... without undue experimentation." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004). In determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue," the Examiner should consider (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art;

(4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands* 858 F.2d 731, 736-7, 8 U.S.P.Q.2d 1400, (Fed. Cir. 1988), citations omitted. As set forth below, the skilled artisan would not have to undertake undue experimentation to make and use the full scope of the claimed invention. Accordingly, Applicants' claimed subject matter is enabled, under 35 U.S.C. § 112, first paragraph.

Regarding the breadth of the claims, Claim 1 has been amended to recite promoters "wherein the first sequence is SEQ ID No. 1 and the second sequence is SEQ ID No. 2 or wherein the first and/or second sequence of the promoter region have a sequence identity of at least 90% to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2." In addition, new Claim 34 recites promoters "wherein the first and/or second sequence of the promoter region hybridize under stringent conditions to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2." Since independent Claims 1 and 34 both recite a functional limitation (*i.e.* a promoter region having specificity for plant epidermis) and a structural limitation (*i.e.* promoter regions with 90% identity to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2 or promoter regions that hybridize under stringent conditions to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2) of the promoter regions, the claims only relate to a well-defined subset of promoter regions. In view of the amendment to the claims, Applicants submit that the breadth of the claims weighs in favor of a finding of enablement.

Applicants submit that as of the effective filing date of the application, the nature claimed subject matter, the state of the prior art, and the level of predictability in the art was such that at the time, the methods needed to practice the invention were well within the skill in the art. Molecular biology methods (including recombinant DNA techniques) and plant biology methods were well known in the art. In particular, the sequences of glutathione-S-transferase A1 (GSTA1) and WIR1a (including introns) were known in the art. As stated in the specification:

> Thus, the present invention relates to a promoter region having specificity for the plant epidermis, comprising a first sequence originating from the promoter of the gene glutathione-S-transferase A1 (GSTA1) and a second sequence originating from the intron of the gene WIR1a. GSTA1 relates to genes as they are described in Dudler et al. (1991), A pathogen-induced wheat gene encodes a protein homologous to glutathione-S-transferases, Mol. Plant Microbe Interact. 4(1), S.

> 14-18. In particular, these genes are genes from wheat; they can, however, also be homologous genes from other cereal plants, in particular from barley, having a comparable expression pattern and a similar gene product. WIR1a denotes genes as they are described in Bull et al. (1992), Sequence and expression of a wheat gene that encodes a novel protein associated with pathogen defense, Mol. Plant Microbe Interact. 5(6), S. 516-519. (*Specification*, at page 3).

Furthermore, it is well-established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. For example, Applicants submit that it is well-established in the art that a skilled artisan would know how to make promoter regions which have at least 90% sequence identity to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2 or promoter regions that hybridize under stringent conditions to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2.

Further, in particular to the claims reciting stringent hybridization conditions, the Patent Office has taken the position that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs." *REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS* at Example 9. Thus, the PTO has taken the position that such claim language does not encompass substantial variation of claimed species. As such, it would not have required undue experimentation for one skilled in the art to make and use the full scope of such a genus of structurally similar nucleic acid molecules.

The level of guidance provided by the specification, particularly in light of the working examples and high level of skill in the art, also weighs heavily in favor of a finding of enablement. The Office Action states that "[n]o guidance has been provided for the specific isolation of GSTA1 promoters and WIR1 introns." (Office Action, at page 7). However working Example 1 clearly teaches the generation of a promoter construct from a GSTA1 promoter and a WIR1a intron:

> Generation was conducted in several steps via the following precursor constructs: pPS1, pPS3, pPS15. All constructs contained the GUS reporter gene, so that they could be tested directly in a transient assay.

pPS1:
A 1.9 kb promoter fragment of the WIR1a gene was cut out of a recombinant pBluescript clone by means of *Pst*I and cloned into the *Pst*I restriction site of an expression cassette before the GUS gene. The expression cassette was based on pBluescript and contained the GUS gene followed by the transcription terminator of the wheat GSTA1 gene. As the GUS gene and the GSTA1 transcription terminator are no longer contained in the final constructs used (see Example 2), a detailed description of this expression cassette is omitted. The resulting construct contained a translational WIR1a::GUS fusion.

pPS3:
With the adaptor primers 5' ATA TAT CTG CAG GGA GCC ACG GCC GTC CAC and 5' TAT CCC GGG CCC GTG CCT GGA CGG GAA, a PCR fragment of about 240 bp was generated and its ends were cut with *Sma*I and *Pst*I (via Adaptor). The genomic WIR1a clone served as PCR template. The PCR fragment contained the last 15 amino acids of the first exon of WIR1a and the intron including splice site acceptor, and was ligated in pPS1, cut with *Pst*I (partially) and *Sma*I and purified by means of agarose gel electrophoresis. The resulting construct contained a translational WIR1a::GUS fusion with the WIR1 intron before the GUS gene. Furthermore, a deletion of amino acids Nos. 18 - 35 of the first exon of WIR1a was introduced in order to prevent the secretion of the WIR1a::GUS fusion protein (by means of removing the signal peptide).

pPS15:
The WIR1a promoter was replaced by a PCR fragment of the GSTA1 promoter. To this end, pPS3 was (partially) digested with *Xho*I and *Sna*BI and the vector band was purified by means of agarose gel electrophoresis. The GSTA1 promoter fragment of about 2.3 kb length was amplified by means of PCR with the adaptor primers 5'ATA TAT CTC GAG TCT AGA ACT AGT GGA TCC and 5'ATA TAT TAC GTA GTT TGT CCG TGA ACT TCA from the genomic GSTA1 clone and cut at the ends with *Xho*I und *Sna*BI. The PCR fragment was ligated with the gel-eluated pPS3 band, resulting in a translational fusion of the intron-containing WIR1a gene fragment with GUS under the control of the GSTA1 promoter.

pPS18:
pPS15 was (partially) digested with *Pst*I and *Sna*BI, the vector band was purified by means of agarose gel electrophoresis and ligated with a double-stranded oligonucleotide (5'GTA CAC AGG CAG CTA GCT CTC GAA ACC TCG CTC GAA ACG CA plus 5'CAT GTG TCC GTC GAT CGA GAG CTT TGG AGC GAG CTT TGC GT). This replaced the part of the WIR1a gene located around the translation start (46 bp upstream to 53 bp downstream of the translation start) with 42 bp of the 5'UTR of the WIR1a gene without the translation initiation codon ATG. The resulting construct contained a transcriptional fusion of the

> intron-containing WIR1a gene fragment with GUS under the control of the GSTA1 promoter. (Specification, pages 19-20)

The Office Action also states the specification does not teach sequences that hybridize under stringent conditions to specific sequences disclosed in the application. However, as disclosed on pages 7-8, the instant specification teaches not only variants of sequences that hybridize under stringent conditions to specific sequences disclosed in the application, but also variants that are at least 90% identical to specific sequences disclosed in the application:

> The present invention also relates to promoter regions having a nucleic acid sequence hybridizing with the nucleic acid sequence given in SEQ ID No. 3 under stringent conditions. In the context of the present invention, the term "hybridization under stringent conditions" means that hybridization is conducted *in vitro* under conditions, which are stringent enough to ensure a specific hybridization. Such stringent hybridization conditions are known to the person skilled in the art and can be taken from the literature (Sambrook et al. (2001), Molecular Cloning: A Laboratory Manual, 3. edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York).
>
> In general, "specifically hybridize" means that a molecule preferentially binds to a specific nucleotide sequence under stringent conditions, if said sequence is present in the form of a complex mixture of (for example total) DNA or RNA. The term "stringent conditions" generally denotes conditions, under which a nucleic acid sequence will preferentially bind to its target sequence and to a considerably smaller extent or not at all to other sequences. Stringent conditions are partially sequence-dependent and will be different under different circumstances. Longer sequences specifically hybridize at higher temperatures. In general, stringent conditions are selected in such a way that the temperature lies about 5°C below the thermal melting point (T_m) for the specific sequence at a defined constant ionic strength and a defined pH value. T_m is the temperature (under defined ionic strength, pH value, and nucleic acid concentration), at which 50% of the molecules complementary to the target sequence hybridize to the target sequence in a state of equilibrium. Typically, stringent conditions are those, wherein the salt concentration is at least about 0.01 to 1.0 M sodium ion concentration (or any other salt) at a pH value of between 7.0 and 8.3 and the temperature is at least 30 °C for short molecules (i.e. for example 10 to 50 nucleotides). In addition, stringent conditions can be achieved by means of adding destabilizing agents, like for example formamide.
>
> Suitable stringent hybridization conditions are, for example, also described in Sambrook et al., vide supra. Thus, hybridization can, for example, occur under the following conditions:

- hybridization buffer: 2 x SSC, 10 x Denhardt's solution (Fikoll 400 + PEG + BSA; ratio 1:1:1), 0,1% SDS, 5 mM EDTA, 50 mM Na_2HPO_4, 250 µg/ml herring sperm DNA; 50 µg/ml tRNA or 0.25 M sodium phosphate buffer pH 7,2, 1 mM EDTA, 7% SDS at a hybridization temperature of 65°C to 68°C
- washing buffer: 0.2 x SSC, 0,1% SDS at a washing temperature of 65°C to 68°C

Preferably, such promoter variants have a sequence identity of at least 50%, preferably at least 70%, particularly preferably at least 90%, and most preferably at least 95% to the promoter sequence given in SEQ ID No. 3 or parts thereof, in relation to the total DNA sequence shown in SEQ ID No. 3. Preferably, the sequence identity of such promoter sequences is determined by means of comparison with the nucleic acid sequence given under SEQ ID No. 3. In case two nucleic acid sequences of different length are compared to each other, the sequence identity preferably relates to the percentage of the nucleotide residues of the shorter sequence, which are identical to the corresponding nucleotide residues of the longer sequence.

***

The percentage degrees of identity given above for SEQ ID No. 3 also apply to the first and second sequences of the promoter region according to the present invention, which are shown in SEQ ID Nos. 1 and 2.

The Office Action also states that no guidance has been provided for any modified sequences that would result in a functional sequence. (Office Action, at pages 7-8). However, as described on pages 5-6, the instant applications teaches regions and/or motifs that should be retained in the promoter regions encompassed by the claims to maintain activity:

> In this context, a "functional part" is understood to denote sequences, which the transcription complex, despite a slightly deviating nucleic acid sequence, can still bind to and cause epidermis-specific expression. Functional parts of a promoter sequence also comprise such promoter variants, whose promoter activity is lessened or enhanced in comparison with the wild-type. In particular, a functional part is, of course, also understood to denote natural or artificial variants of the sequence of the promoter region given in SEQ ID No. 3. Mutations comprise substitutions, additions, deletions, exchanges, and/or insertions of one or more nucleotide residue/s. Within the scope of the present invention, functional parts of the promoter regions comprise naturally occurring variants of SEQ ID No. 3 as well as artificial nucleotide sequences, for example obtained by means of chemical synthesis.
>
> In any case, the promoter used contains a TATA box (positions 2163 to 2169 in SEQ ID Nos. 1 and 3) and preferably also two CAAT boxes (positions 1047 to 1051 or 1895 to 1899 in SEQ ID Nos. 1 and 3). Furthermore, the promoter contains at least one, preferably at least two and three, particularly preferably at

least four, five, and six, and most preferably at least seven or eight of the following sequence motifs:

a) GTGGGGG
b) ACGTGGA
c) TCCACCT
d) TATCCAT
e) CATGCATG
f) TGTAAAG
g) CCTACCA
h) AATAGTA

Preferably, the sequence motifs are located at the positions corresponding to the following positions in SEQ ID Nos. 1 and 3:

- a) 185-191 and 217-223 bp
- b) 455-461 bp
- c) 508-514 bp
- d) 564-570 bp
- e) 1514-1521 bp
- f) 1520-1526 bp
- g) 1569-1575 bp
- h) 1610-1616 bp

Furthermore, the specification provides guidance with respect to measuring promoter activity to ensure the variant promoter region is functional:

> The promoter activity of variants of the promoter region can be measured with the aid of marker genes, whose coding sequence is under the control of the promoter region to be examined. Suitable marker genes are, for example, the β-glucuronidase (GUS) gene from *E. coli*, a fluorescence gene like, for example, the green fluorescence protein (GFP) gene from *Aequoria victoria*, the luciferase gene from *Photinus pyralis* or the β-galactosidase (lacZ) gene from *E. coli*. Absolute promoter activity is determined by means of comparison with a wild-type plant. Tissue or cell specificity can easily be determined by means of comparison of the expression rates of the above-mentioned marker genes in the respective tissues or cells. (Specification at page 6)

In addition, the working examples provide specific techniques that would enable one skilled in the art to transform plants (see, for instance, working example 3) and test for expression and functional activity of the transformed construct (see, for instance, working examples 4-8).

Given the detailed protocols set forth in the working examples and the guidance provided in the specification, the ordinary skilled artisan could readily make and use the claimed invention. The quantity of experimentation to enable one skilled in the art to practice the claimed invention is, if anything, minimal and routine. In particular, claims reciting stringent hybridization conditions are well-established as not encompassing a genus of substantially variation, and as such, the disclosure requirement for enabling one skilled in the art to practice the full scope of the claim is not high.

For the reasons set forth above, Applicants maintain that the skilled artisan could practice the full scope of the claimed invention without undue experimentation. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Discussion of Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 1, 3-18, and 21-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description. The Office Action states that the Applicant has described a method that employs the promoter sequences of SEQ ID No: 3 or 1 and 2. However, the Office Action states that Applicant not described functional parts of the promoter region as to correlate structure and function.

In view of the presently pending claims, Applicants respectfully traverse.

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112 , first paragraph is whether the disclosure "reasonably conveys to artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 2121 USPQ 1089, 1096 (Fed. Cir. 1983); *see also Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. *See e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *Union Oil v. Atlantic Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000).

As noted above, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains. The present invention pertains to the field of recombinant DNA/protein technology, as well as plant technology. It is well-established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made.

As stated above in the discussion of the enablement rejection, the specification describes in detail various regions and/or motifs that should be retained in the promoter regions encompassed by the claims to maintain activity. (See, for example, Specification at pages 5-6). Furthermore, GSTA1 and WIR1a genes were well known in the art. (See, for example, Specification at page 3). As stated in MPEP §2164.05(a):

> The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). *See also* MPEP §2163.

Furthermore, as discussed above with regard to the enablement rejection, Claim 1 has been amended to recite promoters "wherein the first sequence is SEQ ID No. 1 and the second sequence is SEQ ID No. 2 or wherein the first and/or second sequence of the promoter region have a sequence identity of at least 90% to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2." In addition, new Claim 34 recites promoters "wherein the first and/or second sequence of the promoter region hybridize under stringent conditions to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2." Since independent Claims 1 and 34 both recite a functional limitation (*i.e.* a promoter region having specificity for plant epidermis) and a structural limitation (*i.e.* promoter regions with 90% identity to the sequences of SEQ ID No. 1 and/or SEQ ID No. 2 or promoter regions that hybridize under stringent conditions to the sequences of SEQ ID No. 1 and/or SEQ

ID No. 2) of the promoter regions, the claims only relate to a well-defined subset of promoter regions.

Further, in particular to the claims reciting stringent hybridization conditions, the Patent Office has taken the position that "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs." *REVISED INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS* at Example 9. Thus, the PTO has taken the position that such claim language does not encompass substantial variation of claimed species, and, as such, is sufficient to meet the written description requirement. As such, one skilled in the art would have readily recognized that the inventors were in possession of the full scope of the claims reciting such stringent hybridization conditions.

In view of the above, Applicants submit that they have satisfied the written description requirement for the pending claims based on the high level of structural relatedness of the species within the claimed genera, the knowledge of sequences by those skilled in the art, Applicants' teachings of structural motifs related to functional properties, and Applicants' working Examples and teachings on variants with functional activity. Applicants submit that this disclosure would allow one of skill in the art to recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus. In particular, claims reciting stringent hybridization conditions are well-established as not encompassing a genus of substantial variation, and, accordingly, such recitation is considered sufficient to meet the written description requirement.. Hence, Applicants respectfully request that the PTO reconsider and withdraw the written description rejection under 35 U.S.C. §112.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope, the Applicants are not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to

be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues might be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 4-Aug-08

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